Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the effect of sublingual Misoprostol versus intravenous Oxytocin in the management of the third stage of labor

Protocol summary

Summary

This study will be performed on 200 primiparous women in Al-zahra hospital of Rasht, Iran. The women will be divided into two groups randomly. One group (Intervention group) will be treated with 400 microgram of sublingual Misoprostol plus 20 ml of distilled water as placebo and another group (control group) will be treated with 20ml of Intravenous Oxytocine plus two sublingual placebo tablet. The drugs will be prescribed by a delivery agent to mothers immediately after neonatal birth. The amount of lost blood in third stage of delivery will be measured by scaled dish. Also we weigh Blood gauzes during the repair of episiotomy by a digital scale. Additionally Patients hemoglobin level will be evaluated before and 12 hours after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902293964N1**
Registration date: **2010-08-23, 1389/06/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-08-23, 1389/06/01

Registrant information

Name

Fereshte Fakoor

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

fakoor@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research – Guilan university of medical sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of sublingual Misoprostol versus intravenous Oxytocin in the management of the third stage of labor

Public title

Comparing the effect of sublingual Misoprostol versus intravenous Oxytocin in the management of the third stage of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primiparity, informed consent, entering the labour spontaneously – Exclusion criteria: multyparity, be longed induction (>12 hours), past history of hemorrhagic disorders (like as hemophilia, von Willebrand s disease, and so forth), poly hydramnious, Large episiotomy, internal diseases (like as Asthma, preeclampsia, cardiac diseases and so forth), etc.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice Chancellor for research – Guilan university of medical sciences
Street address
Vice Chancellor for research of Guilan university of medical sciences, Namjoo street
City
Rasht
Postal code
Approval date
empty
Ethics committee reference number
1694

Health conditions studied

1

Description of health condition studied
intrapartum haemorrhage
ICD-10 code
O67.8
ICD-10 code description
Other intrapartum haemorrhage

Primary outcomes

1

Description
Hematocrit decline
Timepoint
before delivery twelve hours after that
Method of measurement
hemoglobin and Hematocrit level

2

Description
postpartum hemorrhage
Timepoint
During delivery, one and twelve hours after that
Method of measurement
By using scaled dish, weight of bloody gauzes and cloths

Secondary outcomes

1

Description
third part of delivery time
Timepoint
During delivery and one hour after that
Method of measurement
Measuring of neonatal birth time until the placenta full evacuation

2

Description
frequency of need for blood transfusion
Timepoint
Before delivery and 12 hours after that
Method of measurement
More than 10 percent decline in Hb and Hct level, rising of pulse rate

3

Description
maternal complications frequency
Timepoint
One, four and twelve hours after delivery
Method of measurement
Questionnaire

4

Description
uterine Atony
Timepoint
During delivery , one, 4 and 12 hours after that
Method of measurement
Sever of vaginal bleeding after delivery

Intervention groups

1

Description
Intervention group: 400 microgram of sublingual Misoprostol plus 20 ml of distilled water (as placebo)
Category
Treatment - Drugs

2

Description
Control group: 20 ml of intravenous Oxytocine plus two tablet of sublingual placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital, Guilan university of medical sciences
Full name of responsible person
Street address
Namjoo Street
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice chancellorship - Guilan university of medical sciences
Full name of responsible person
Dr. Abdolrasol Sobhani
Street address
Namjo street
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research vice chancellorship - Guilan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Reproductive Health Research center, Guilan University of Medical Sciences
Full name of responsible person
Fereshte Fakoor
Position
Assistant professor of Obstetric and Gynecology
Other areas of specialty/work
Street address
Reproductive Health Research center, Department of Ob & Gyn, Alzahra Hospital, Namjo street
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Reproductive Research Health Center, Guilan University of Medical Sciences
Full name of responsible person
Seyede Fatemeh Dalil Heirati
Position
Bs in Midwifery
Other areas of specialty/work
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fatemehdalil@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty